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US 5967986 A

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(54) Abstract Title
Spiral flow testing

(57) A tube 11 with an internal spiral flow-inducing formation is mounted within a flow system. The flow system has upstream 12 and downstream 13 tubing that deliver fluid to and from the tube 11. Transverse flow velocity is measured downstream by observing tomographic slices within a length 'L'. The tube 11 is characterised by computing a transverse flow signature from the measured velocity. The fluid may be blood or a suitable substitute with comparable density, viscosity, and acoustic refractive index. The flow velocity may be measured by Doppler ultrasound. A stenosis (figure 3) may be inserted downstream of the tube to determine the effect it has on the spiral flow induced by the tube. The effect is determined by introducing pressure sensing locations 14 into the upstream and downstream tubing.

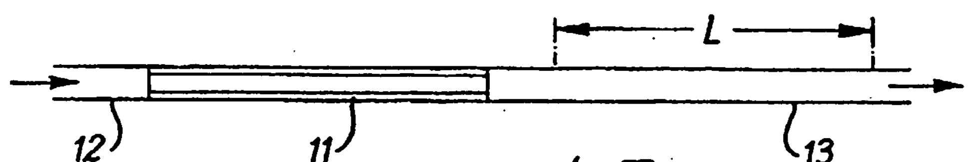

FIG. 1

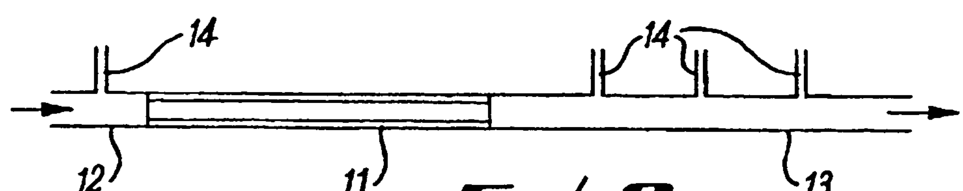

FIG. 2

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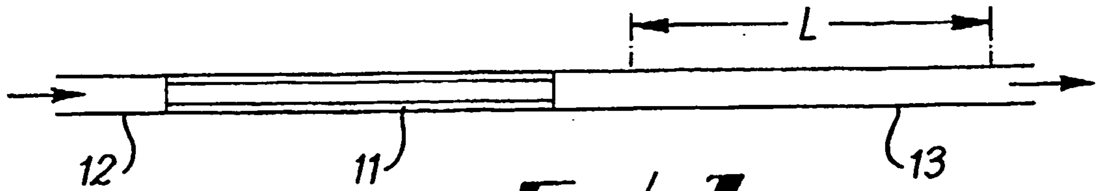

FIG. 1

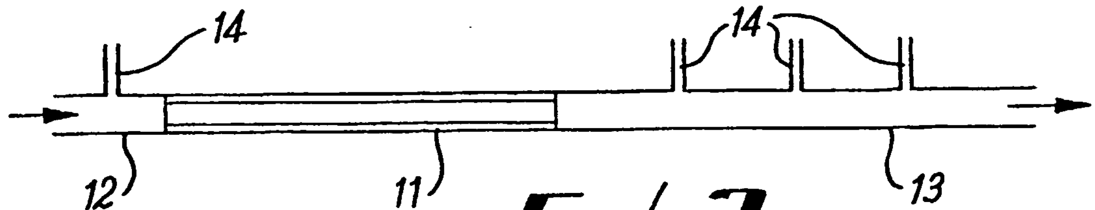

FIG. 2

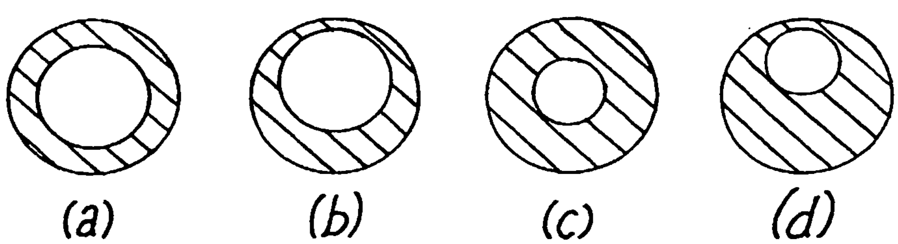

FIG. 3

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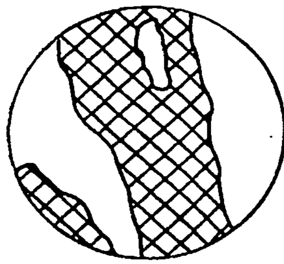

FIG. 4

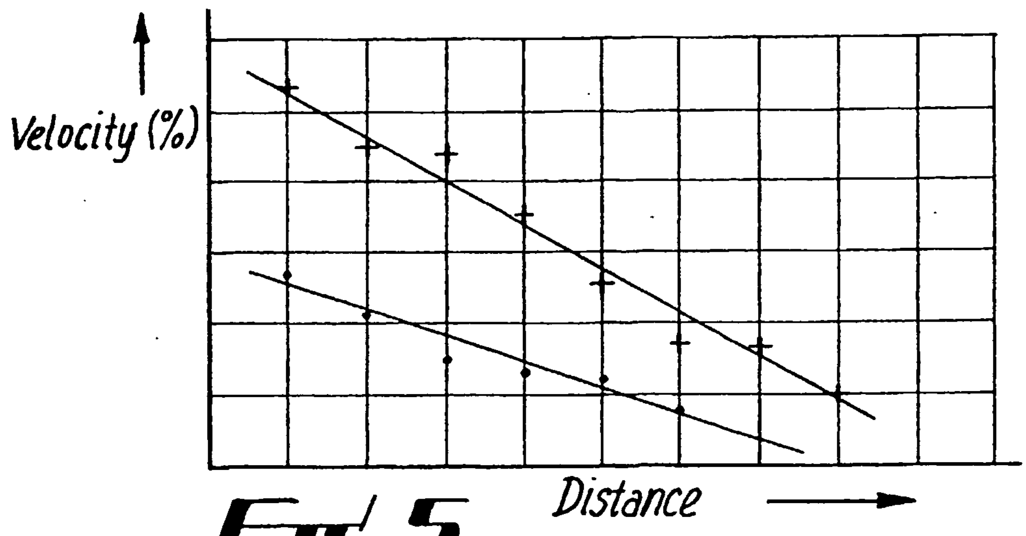

FIG. 5

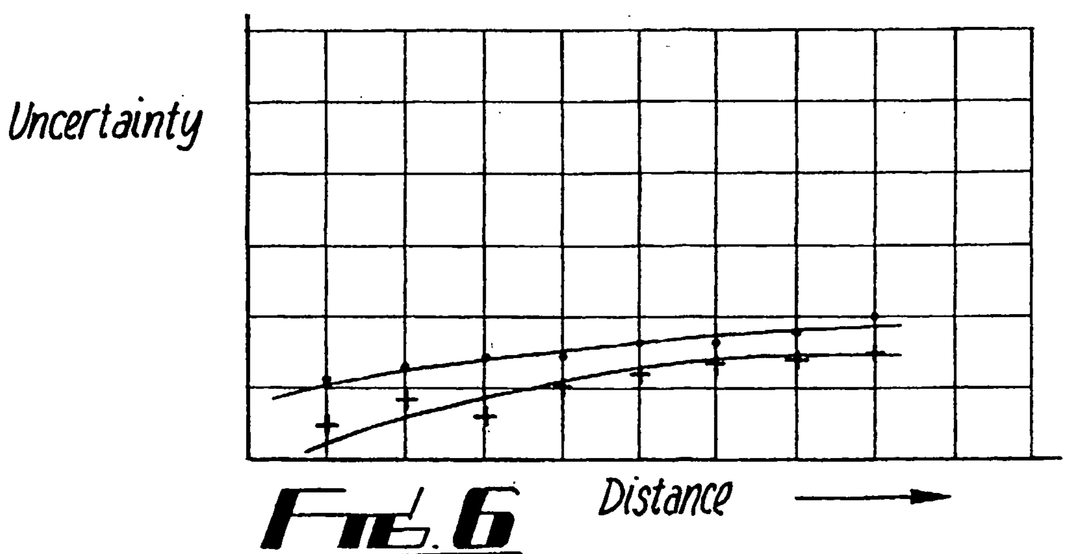

FIG. 6

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Spiral Flow Testing

This invention relates to spiral fluid flow in tubes.

In WO 00/38591 is disclosed the use of tubing, for example, blood flow tubing, with internal spiral (or helical) formation such as to improve flow through the tubing is at least some respects. In particular, spiral flow induced by a spiral formation in an artery or graft can reduce or eliminate dead flow regions and turbulence, leading to reduced tendency of stenosis. The same effect is observed in industrial tubing and pipes.

The effect depends upon the dimensions of the tubing and the properties of the fluid flow, its density, viscosity and its speed, as well as on the nature of the spiral formation.

For a given fluid flow, the problem is to specify an internal spiral formation, of a tube of given dimensions, that produces a beneficial effect; a further problem is to specify a formation which optimises the effect. Given all the possible variations in tube dimensions and fluid properties, as well as the number of different ways ion which a spiral formation can be realised, and given the difficulty of even observing spiral flow, especially in narrow bore tubing, the trial and error approach is often tedious, and cannot ever be guaranteed to produce the best design, since there will always be some configurations that remain unexplored.

The present invention provides a means for testing spiral flow in tubes that will help in the specification of optimal or near optimal spiral formation.

The invention comprises a method for evaluating spiral flow of a given fluid in tubes with spiral formation inducing spiral flow, comprising:

- mounting a tube for testing in a flow system;

- flowing through the tube a fluid which is or is equivalent to said given fluid or which has properties related in known ways to those of said given fluid;

- measuring transverse flow velocity downstream of the tube in a manner which does not affect flow in the tube; and

- characterising the tube by computing a characteristic transverse flow signature from the measurement of transverse flow velocity,

The transverse flow velocity may be measured by Döppler ultrasound.

The flow system may comprise upstream and downstream tubing delivering fluid to and receiving it from the tube. The upstream tubing may be such as deliver specific amounts of turbulence in the flow and non-rotational flow to the tube, and the downstream tubing may be such as not to induce turbulence and/or rotation which could be propagated upstream. Smooth-walled tubing, such as silicon or silicon-lined or silicone treated tubing will usually be found suitable.

The flow system may comprise a source for the fluid and pressure means to provide a pressure head in the fluid. The pressure means may comprise a fluid reservoir elevated above the tube, and/or a pump.

Usually, the fluid will be a liquid. For testing blood flow tubing, the fluid will be blood, or, preferably, a liquid simulating blood, as by having comparable density and viscosity. For Döppler ultrasound measurements, the fluid may also have comparable acoustic refractive index.

The method may also involve measurement of fluid pressure. This may be measured upstream and/or downstream of the tube.

The effect of a stenosis may be observed by making measurements with and without such. An apertured plug may be inserted in the downstream tube of a flow system for this. Testing the effect of different stenosis values (stenosis value may be defined as the ratio of plug aperture to tube area) may be done by inserting a series of plugs with different stenosis values. Ultrasound measurements may be made on the downstream tubing, just downstream of the tube, and at differing distances from it, but upstream of the stenosis, to indicate how a spiral form graft will be affected over time by developing atherosclerosis, for example.

For measurement of pulsatile flow, such as blood flow, clearly pulsatile flow conditions can be imposed by control of a pump or a valve. Snapshot and/or time sequence measurements may be made.

Measurement, especially Döppler ultrasound measurement, may give, for a tomographic slice of the tubing, a distribution of transverse velocity values against radius from the axis of the tubing. Such a distribution may be analysed by any convenient method. For example, the distribution may be regarded as an image, which may be bit-mapped and subjected to image processing techniques.

A Characteristic Transverse Flow Signature (CTFS) may be assessed from transverse velocity profiles by computing:

1) spiral velocity = measured peak transverse velocity
2) spiral statistical uncertainty

The predicted peak transverse velocity is the transverse velocity calculated from the input conditions assuming the spiral flow is perfect, i.e. that there is no flow in the radial

direction. The spiral statistical uncertainty is the average of the statistical uncertainty for the transverse velocity profile expressed as a percentage of peak transverse velocity. The smaller the spiral statistical uncertainty, the more isotropic is the spiral flow.

The invention also comprises tubes having an internal spiral formation which is determined by means of a method according to the invention outlined above.

For blood flow tubing, which is to say, grafts, whether modified natural or artificial tubing, and possibly also tubing of devices such as heart-lung machines and giving sets, the method according to the invention indicates that single spiral formation tubing is best, and that downstream stenosis of no more than 44% stenosis value is sufficient to cancel any spiral flow induced by the spiral formation tube - this is rectangular linear profile stenosis. This is already a useful result in terms of aftercare of patients who have received grafts, and indicates that a programme of regular Döppler ultrasound or other measurement of spiral flow *in vivo* is a useful check on the viability of grafts, not to mention the indication that a graft with a single start thread would be the preferred choice for implantation, whether as an arterial bypass graft or as a leg artery replacement.

The internal spiral formation, in blood flow tubing, may be that of a stent. WO? referred to above discloses stents with spiral formations that induce spiral flow in veins or arteries and such stents may also be assessed using the method of the invention. The set-up may be designed to mimic the site at which the stent will be implanted, by suitable choice of tube, and inlet and outlet tubing, and different stents tested, or a reconfigurable stent tested in different configurations, in order to optimise stent performance.

Methods according to the invention for evaluating spiral flow of a given fluid in tubes with spiral formation inducing spiral flow will now be described with reference to the accompanying drawings in which:

Figure 1 is a diagrammatic illustration of an experimental set-up;

Figure 2 is an illustration showing the set-up of Figure 1 in another measurement mode;

Figure 3 shows four different stenoses for the measurement mode of Figure 2;

Figure 4 is a diagrammatic cross-section of a tube under investigation, showing the measurements made by the Döppler ultrasound technique;

Figure 5 is a graph showing spiral velocity against distance for two designs of graft; and

Figure 6 is a graph showing spiral statistical uncertainty against distance for the two grafts of Figure 5.

The drawings illustrate a method for evaluating spiral flow of a given fluid in tubes with spiral flow formation inducing spiral flow, comprising:

- mounting a tube 11 for testing in a flow system;
- flowing through the tube 11 a fluid which is, or which is equivalent to said given fluid or which has properties related in known ways to those of said given fluid;
- measuring transverse flow velocity downstream of the tube 11 in a manner which does not affect flow in the tube 11; and

- characterising the tube 11 by computing a characteristic transverse flow signature from the measurement of transverse flow velocity,

A preferred method for measuring transverse flow velocity uses Döppler ultrasound techniques. Equipment for this is commercially available, and details will not be elaborated here, nor is it shown in the drawings. The techniques are applied in a flow system comprising upstream 12 and downstream 13 tubing delivering fluid to and receiving it from the tube 11. Of particular interest is to see how spiral flow induced in the tube 11 is maintained downstream, and tomographic slices of fluid are observed at various positions in the downstream tubing 13, within an available length "L".

The flow system comprises a source for the fluid and pressure means to provide a pressure head in the fluid, neither of which is illustrated. The pressure means may comprise a fluid reservoir elevated above the tube 11 and/or a pump.

The fluid will usually be a liquid, and a liquid of particular interest is blood, it having been realised that the way blood flows in veins and arteries can have a major influence on the continued patency thereof. WO 00/38591 discusses how spiral formation in blood vessels can prevent build up of deposits on their walls to maintain healthy flow and militate against the formation of clots. Blood could be used for testing, but preferred is a liquid that simulates blood without the problems of maintaining its viability over prolonged tests. A mix of Shelley fluid and ATS mimics blood in terms of density, viscosity and acoustic refractive index, and is ideal for Döppler ultrasound measurements.

In addition to the measurement of transverse velocity, it is also considered important to determine how the tube 11 affects pressure in the flow system, and, in particular, how downstream stenosis affects the spiral flow induced by the tube 11. The system of Figure 1 is modified for this purpose as shown in Figure 2 by introducing pressure

sensing locations 14 at various positions in the delivery and receiving tubing 12, 13. Typical testing stenoses are illustrated in Figure 3 in cross section, (a) and (b) being coaxial with stenosis values (ratio of hatched blocked area to whole) of 75% and 44% respectively, (c) and (d) being off-axis versions of the same stenosis values.

In blood flow tubing, flow is pulsatile, and the flow system is adapted to produce pulsatile flow by suitable motor or valve control. Measurements can be snapshot or continuous over time.

Figure 4 shows a Döppler ultrasound scan. These are usually two-colour scans with one colour (hatched area) indicating flow towards and the other colour (unhatched) indicating flow away from the sound source, the intensity of the colour (which cannot be shown in the drawing) indicating velocity. The ultrasound image can be processed using conventional image processing techniques to produce a distribution of transverse velocity values over the scanned area, which can then be subjected to analysis to yield a Characteristic Transverse Flow Signature (CTFS). While, for different purposes, different properties might be considered to be more or less important, for blood flow tubing, the spiral velocity and the spiral statistical uncertainty combine to give a good indication of the quality of a graft.

That significant differences between even apparently similar tube configurations can be detected by the method of the invention is demonstrated by reference to Figures 4 and 5 which show, for two different grafts, spiral velocity against distance (Figure 4) and spiral statistical uncertainty against distance (Figure 5).

Graft 1 was an 8mm diameter graft with a single internal fin, of helix angle 8°, the depth of the fin being 2mm. Graft 2 was a similar graft, but with two internal fins. It will be seen that the Spiral velocity is higher for Graft 1, and the Spiral statistical uncertainty

lower than for Graft 2, indicating that Graft 1 is the better graft, at least by the applied standards.

A flow system according to the invention will have desirably a sufficiently flexible design to accommodate grafts of different lengths and to investigate flow in downstream tubing at different distances, perhaps up to half a metre or more, from the graft under investigation. Fixtures and fittings will be provided facilitating the connection of tube of different diameters and for the insertion of stenoses. For the testing of stents, facilities will be provided for accommodating stents of different designs and for actuating stents which need to be deployed and manipulated in veins and arteries.

Of course, while the invention has been described primarily in the context of blood flow tubing, this reflects the particular interest of the inventors. The method is adaptable to the testing of other spiral formation tubing, e.g. for industrial uses, by a change in scale and in the precise specification of dimensions, fixtures and fittings, as well as the measurement techniques used.

CLAIMS

1 A method for evaluating spiral flow of a given fluid in tubes with spiral formation inducing spiral flow, comprising:

- mounting a tube for testing in a flow system;
- flowing through the tube a fluid which is, or which is equivalent to, or which is related in a known way to, said given fluid;
- measuring transverse flow velocity downstream of the tube in a manner which does not affect flow in the tube; and
- characterising the tube by computing a characteristic transverse flow signature from the measurement of transverse flow velocity.

2 A method according to claim 1, I which the transverse flow velocity is measured by Döppler ultrasound.

3 A method according to claim 1 or claim 2, in which the flow system comprises upstream and downstream tubing delivering fluid to and receiving fluid from the tube.

4 A method according to claim 3, in which the flow system comprises a source for the fluid and pressure means to provide a pressure head in the fluid.

5 A method according to claim 4, in which the pressure means comprise a fluid reservoir elevated above the tube.

6 A method according to claim 4 or claim 5, in which the pressure means comprise a pump.

7 A method according to any one of claims 1 to 6, in which the fluid is a liquid.

8 A method according to claim 7, in which the tube is blood flow tube and the liquid simulates blood.

9 A method according to claim 6 or claim 7, in which the fluid is a liquid simulating said given fluid by having comparable density and viscosity.

10 A method according to claim 9, in which the liquid also has comparable acoustic refractive index.

11 A method according to any one of claims 1 to 10, in which fluid pressure is measured.

12 A method according to claim 11, in which fluid pressure is measured upstream and downstream of the tube.

13 A method according to any one of claims 1 to 12, in which a stenosis is inserted downstream of the tube and its effect on spiral flow observed.

Amendments to the claims have been filed as follows

1 A method for evaluating spiral flow of a fluid in tubes with spiral formation inducing spiral flow, comprising:

- mounting a tube for testing in a flow system;
- flowing through the tube a fluid which is, or which is equivalent to, or which is related in a known way to, said fluid;
- measuring transverse flow velocity downstream of the tube in a manner which does not affect flow in the tube; and
- characterising the tube by computing a characteristic transverse flow signature from the measurement of transverse flow velocity.

2 A method according to claim 1, in which the transverse flow velocity is measured by Döppler ultrasound.

3 A method according to claim 1 or claim 2, in which the flow system comprises upstream and downstream tubing delivering fluid to and receiving fluid from the tube.

4 A method according to claim 3, in which the flow system comprises a source for the fluid and pressure means to provide a pressure head in the fluid.

5 A method according to claim 4, in which the pressure means comprise a fluid reservoir elevated above the tube.

6 A method according to claim 4 or claim 5, in which the pressure means comprise a pump.

7 A method according to any one of claims 1 to 6, in which the fluid is a liquid.

8 A method according to claim 7, in which the tube is blood flow tube and the liquid simulates blood.

9 A method according to claim 6 or claim 7, in which the fluid is a liquid simulating the fluid under evaluation by having comparable density and viscosity.

10 A method according to claim 9, in which the liquid also has comparable acoustic refractive index.

11 A method according to any one of claims 1 to 10, in which fluid pressure is measured.

12 A method according to claim 11, in which fluid pressure is measured upstream and downstream of the tube.

13 A method according to any one of claims 1 to 12, in which a stenosis is inserted downstream of the tube and its effect on spiral flow observed.

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Application No: GB 0122476.5
Claims searched: 1-13

Examiner: Ian Blackmore
Date of search: 31 January 2002

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

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Int Cl (Ed.7): A61B 8/06, 8/08. A61F 2/06. G01F 1/66, 1/72, 1/80. G01P 5/00. G01B 17/06, 17/08.

Other: Online: EPODOC, JAPIO, WPI.

Documents considered to be relevant:

Category	Identity of document and relevant passage	Relevant to claims
A	WO 00/38591 A (TAYSIDE) see whole document	-
A	US 6053873 A (BIOSENSE) see figure 2	-
A	US 5967986 A (VASCUSENSE) see figures 7-9	-

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.